



FORM PTO - 1449

INFORMATION DISCLOSURE  
STATEMENT

ATTORNEY DOCKET NO.: INL-054DV

APPLICANTS: Dahlbäck et al.

SERIAL NO.: 10/037,296

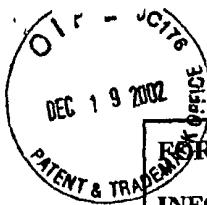
FILING DATE: December 21, 2001

GROUP: 1644

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## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
Dry	A1	4,622,389	11/11/86	Nagasawa <i>et al.</i>	530	331	05/09/85
	A2	4,692,406	09/08/87	Becker <i>et al.</i>	435	13	08/20/84
	A3	4,755,461	07/05/88	Lawson <i>et al.</i>	435	13	04/17/86
	A4	4,849,403	07/18/89	Stocker <i>et al.</i>	514	2	05/09/86
	A5	5,001,069	03/19/91	Bartl <i>et al.</i>	436	86	10/04/88
	A6	5,051,357	09/24/91	Hassouna	435	13	08/21/89
	A7	5,059,525	10/22/91	Bartl <i>et al.</i>	435	13	05/29/90
	A8	5,147,805	09/15/92	Preda <i>et al.</i>	436	86	06/29/90
	A9	5,169,786	12/08/92	Carroll <i>et al.</i>	436	69	12/19/89
	A10	5,187,067	02/16/93	Koike <i>et al.</i>	435	7.9	03/14/91
	A11	5,200,322	04/06/93	Matsumoto	435	13	02/28/91
	A12	5,223,427	06/29/93	Edginton <i>et al.</i>	435	240.27	03/09/88
	A13	5,254,350	10/19/93	Barrow <i>et al.</i>	424	570	07/22/91
	A14	5,270,451	12/14/93	Hawkins <i>et al.</i>	530	381	08/06/92
	A15	5,308,756	05/03/94	van de Waart <i>et al.</i>	435	13	11/20/91
	A16	5,314,695	05/24/94	Brown	424	450	10/29/91
	A17	5,358,853	10/25/94	Butler <i>et al.</i>	435	13	08/03/92
	A18	5,374,617	12/20/94	Morrissey <i>et al.</i>	514	8	05/13/92
	A19	5,391,380	02/21/95	Barrow <i>et al.</i>	424	570	05/14/93
	A20	5,405,946	04/11/95	Griffin <i>et al.</i>	530	380	12/02/92
	A21	5,418,141	05/23/95	Zweig <i>et al.</i>	435	13	05/06/94
	A22	5,426,031	06/20/95	Hawkins <i>et al.</i>	435	13	05/25/93
	A23	5,439,802	08/08/95	Rosén	435	13	01/14/92
	A24	5,443,960	08/22/95	Dahlbäck	435	13	05/27/94
	A25	5,472,850	12/05/95	Morrissey	435	13	04/10/91
EXAMINER <i>David A Saenzas</i>				DATE CONSIDERED <i>12/16/03</i>			



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EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
<i>✓</i>	A26	5,502,651	03/26/96	Jackson et al.	364	509	05/02/94
	A27	5,504,064	04/02/96	Morrissey et al.	514	8	02/19/93
	A28	5,504,067	04/02/96	Morrissey et al.	514	8	10/12/94
	A29	5,506,112	04/09/96	Lang et al.	435	13	01/10/92
	A30	5,508,170	04/16/96	Butler et al.	435	13	06/03/94
	A31	5,525,478	06/11/96	Matschiner	435	13	06/07/95
	A32	5,597,700	01/28/97	Konstantinov et al.	435	7.92	04/28/94
	A33	5,643,739	07/01/97	Varadi et al.	435	13	05/01/95
	A34	5,705,395	01/06/98	Griffin et al.	436	69	11/14/94
	A35	5,716,795	02/10/98	Matschiner	435	13	01/03/96
	A36	5,726,028	03/10/98	Kraus	435	13	08/04/95
	A37	5,753,510	05/19/98	Kraus	436	16	11/07/95
	A38	5,766,869	06/16/98	Arkel et al.	435	13	11/27/96
	A39	5,780,255	07/14/98	Preda	435	23	06/09/95
	A40	5,834,223	11/10/98	Griffin et al.	435	13	12/18/97
	A41	5,858,724	01/12/99	Novy, Jr. et al.	435	69.6	07/16/96
	A42	5,874,256	02/23/99	Bertina et al.	435	69.6	02/21/97
	A43	6,083,757	07/04/00	Griffin et al.	436	69	11/10/98
<i>✓</i>	A44	6,203,816B1	03/20/01	Brown	424	450	04/24/95

FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
<i>✓</i>	B1	0 229 234 A1	07/22/87	EP	—	—	10/16/86	English	No
<i>✓</i>	B2	0 271 810 A2	06/22/88	EP	—	—	12/08/87	No	Yes

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EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
Dus	B3	0 286 323 B1	12/15/93	EP	—	—	03/31/88	No	Yes
	B4	0 434 377 B1	08/23/95	EP	—	—	12/18/90	No	Yes
	B5	88/07543	10/06/88	PCT	—	—	03/29/88	No	Yes
	B6	90/11368	10/04/90	PCT	—	—	03/19/90	No	Yes
	B7	91/01382	02/07/91	PCT	—	—	07/04/90	No	Yes
	B8	91/01383	02/07/91	PCT	—	—	07/5/90	No	Yes
	B9	91/02812	03/07/91	PCT	—	—	08/06/90	No	Yes
	B10	92/08479	05/29/92	PCT	—	—	11/04/91	No	Yes
	B11	93/01209	01/21/93	PCT	—	—	07/02/92	No	Yes
	B12	93/07492	04/15/93	PCT	—	—	09/25/92	No	Yes
	B13	93/10261	05/27/93	PCT	—	—	05/13/92	No	Yes
	B14	93/13211	07/08/93	PCT	—	—	12/29/92	No	Yes
	B15	93/23074	11/25/93	PCT	—	—	05/12/93	No	Yes
	B16	95/21938	08/17/95	PCT	—	—	02/14/95	No	Yes

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
Dus	C1	Amer <i>et al.</i> "Impairment of the Protein C Anticoagulant Pathway in a Patient with Systemic Lupus Erythematosus, Anticardiolipin Antibodies and Thrombosis," <u>Thrombosis Research</u> , 57:247-258 (1990).
	C2	Amiral <i>et al.</i> "New Direct Assay of Free Protein S Antigen Using Two Distinct Monoclonal Antibodies Specific for the Free Form," <u>Blood Coag. Fibrin.</u> , 5:179-186 (1994).
	C3	"Antigen-Antibody Crossed Electrophoresis," <u>Analytical Biochemistry</u> , 10(2):358-361 (1965).
	C4	Andrews <i>et al.</i> "Conservation of Tissue Factor Primary Sequence Among Three Mammalian Species," <u>Gene</u> , 98:265-269 (1991).
	C5	Bader <i>et al.</i> "Multicentric Evaluation of a New PT Reagent Based on Recombinant Human Tissue Factor and Synthetic Phospholipids," <u>Thromb. Haemost.</u> , 71(3):292-299 (1994).

EXAMINER David A Seemiller

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OTHER ART, JOURNAL ARTICLES, ETC.

<i>Dahl</i>	C6	Baele <i>et al.</i> "Comparison of a Recombinant Thromboplastin with Thrombotest™ for Oral Anticoagulant Control," <u>Haemost.</u> , 26:11-15 (1996).
	C7	Bauer "Hypercoaguability-A New Cofactor in the Protein C Anticoagulant Pathway," <u>New England Journal of Medicine</u> , 330:566-567 (1994).
	C8	Beauchamp <i>et al.</i> "High Prevalence of a Mutation in the Factor V Gene Within the U.K. Population: Relationship to Activated Protein C Resistance and Familial Thrombosis," <u>British J. of Haemost.</u> , 88:219-222 (1994).
	C9	Beck <i>et al.</i> "Protein C: ein Inhibitor der Blutgerinnung," <u>Diagnose &amp; Labor</u> , 38:35-42 (Abstract in English) (1988).
	C10	Bertina "Specificity of Protein C and Protein S Assays," <u>Res. Clin. Lab.</u> , 20:127-138 (1990).
	C11	Bertina <i>et al.</i> "Mutation in Blood Coagulation Factor V Associated with Resistance to Activated Protein C," <u>Nature</u> , 369:64-67 (1994).
	C12	Bertina <i>et al.</i> "Determination of Plasma Protein S - The Protein Cofactor of Activated Protein C," <u>Thrombosis Haemostasis</u> , 53:268-272 (1985).
	C13	Blangero <i>et al.</i> "Normal Activated Protein C Response has a Large Genetic Component," <u>Florence</u> , PS-920, p. 226 (6/9/97).
	C14	Blangero <i>et al.</i> "Genetic Factors Influence Quantitative Variation in Tissue Factor Pathway Inhibitor," <u>Florence</u> , PS-1666, p. 409 (1997).
	C15	Blombäck <i>et al.</i> "Chromogenic Peptide Substrates in the Laboratory Diagnosis of Clotting Disorders," <u>Haemostasis and Thrombosis</u> , Bloom and Thomas (eds.), 2 <sup>nd</sup> ed, 967-981 (1987).
	C16	Boyer-Neumann <i>et al.</i> "Comparison of Functional Assays for Protein S: European Collaborative Study of Patients with Congenital and Acquired Deficiency," <u>Thromb. and Haemost.</u> , 70(6):946-950 (1993).
	C17	Chromogenix, Coatest APC-Resistance Kit instructions, May-1993.
	C18	Chromogenix, Coatest APC Resistance Kit Brochure, June 1993.
	C19	Comp "Laboratory Evaluation of Protein S Status," <u>Seminars in Thromb. and Haemost.</u> , 16(2):177-181 (1990).
	C20	Comp <i>et al.</i> "An Abnormal Plasma Distribution of Protein S Occurs in Functional Protein S Deficiency" <u>Blood</u> , 67(2):504-508 (1986).
	C21	Cornillon <i>et al.</i> "Rat Coagulation Factor V Purification and Production of the Monospecific Antiserum," <u>Comp. Biochem. Physiol.</u> , 83B, 2: 397-401 (1986).
	C22	"Correlation of the APC Ratio with Free Protein S Antigen and with Protein C Activity" Appendix 5, 3 pages (Publication date not known).
	C23	Cripe <i>et al.</i> "Structure of the Gene for Human Coagulation Factor V," <u>Biochemistry</u> , 31: 3777-3785 (1992).

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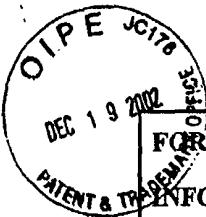
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## OTHER ART, JOURNAL ARTICLES, ETC.

✓ C24	Dahlbäck "Protein S and C4b-Binding Protein: Components Involved in the Regulation of the Protein C Anticoagulant System" <i>Thromb. Haemost.</i> , 66(1):49-61 (1991).
C25	Dahlbäck et al. "Primary Structure of Bovine Vitamin K-Dependent Protein S" <i>Proc. Natl. Acad. Sci.</i> , 83:4199-4203 (1986).
C26	Dahlbäck et al. "Characterization of Functionally Important Domains in Human Vitamin K-Dependent Protein S Using Monoclonal Antibodies" <i>J. Biol. Chem.</i> , 265(14):8127-8135 (1990).
C27	Dahlbäck, et al. "The Protein C Anticoagulant System" <i>The Molecular Basis of Blood Disease</i> , W.B. Saunders Company, Philadelphia, PA, 599-627 (1994).
C28	Dahlbäck et al. "Resistance to Activated Protein C, the FV:Q <sup>506</sup> Allele, and Venous Thrombosis," <i>Ann. Hematol.</i> , 72:166-176 (1996).
C29	Dahlbäck "New Molecular Insights into the Genetics of Thrombophilia. Resistance to Activated Protein C Caused by Arg <sup>506</sup> to Gln Mutation in Factor V as a Pathogenic Risk Factor for Venous Thrombosis," <i>Thromb. Haemost.</i> , 74(1):139-148 (1995).
✓ C30	Dahlbäck "Factor V Gene Mutation Causing Inherited Resistance to Activated Protein C as a Basis for Venous Thromboembolism," <i>J. Intern. Med.</i> , 237:221-227 (1995).
C31	Dahlbäck et al. "Inherited Resistance to Activated Protein C is Corrected by Anticoagulant Cofactor Activity Found to be a Property of Factor V," <i>Proc. Natl. Acad. Sci.</i> , 91:1396-1400 (1994).
C32	Dahlbäck "A New Model for Coagulation Factor V Suggesting a Unique Mechanism of Activation," <i>Scand. J. Clin. Lab. Invest.</i> , 48, Suppl. 191:47-61 (1988).
C33	Dahlbäck "Factor VIII Defect Associated with Familial Thrombophilia," <i>Thrombosis &amp; Haemostasis</i> , 65, Abstract 39:658 (1991).
C34	Dahlbäck et al. "Familial Thrombophilia Due to a Previously Unrecognized Mechanism Characterized by Poor Anticoagulant Response to Activated Protein C: Prediction of a Cofactor to Activated Protein C," <i>Proc. Natl. Acad. Sci.</i> , 90:1004-1008 (1993).
C35	Dahlbäck "Thrombophilia: The Discovery of Activated Protein C Resistance," <i>Advances in Genetics: Incorporating Molecular Genetic Medicine</i> , Academic Press, (Hall et al. eds.), 135-175 (1995).
C36	Dahlbäck et al. "A Natural Anticoagulant Pathway: Proteins C, S, C4b-Binding Protein and Thrombomodulin," <i>Haemostasis and Thrombosis</i> (Bloom et al. eds.), 3 <sup>rd</sup> edition, Churchill Livingstone, 671-698 (1994).
C37	Dahlbäck "The Protein C Anticoagulant System: Inherited Defects as Basis for Venous Thrombosis," <i>Thrombosis Research</i> , 77:1-43 (1995).
C38	D'Angelo "7 Prothrombin Time Standardization: The Problem of the Control Plasma," <i>Eur. J. Clin. Chem. Clin. Biochem.</i> , 33(12):1019-1022 (1995).
C39	Denson et al. "Validity of the INR System for Patients with Liver Impairment," <i>Thromb. Haemost.</i> , 73(1):162 (1995).
✓ C40	Deutsche Norm, DIN 58 911 "Kalibrierung von Gerinnungszeit-Meßverfahren," 3 pages (English translation provided) (1988).

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✓	C41	Deutsche Norm DIN 58 939 "Refererzplasma," 4 pages (English translation provided) (1987).
	C42	Diagnostika Stago "STACLOT® PROTEIN C Additional Information," 1 page (Publication date unknown).
	C43	Diagnostica Stago "STACLOT® PROTEIN S Additional Information," 1 page (Publication date unknown).
	C44	DiScipio <i>et al.</i> "A Comparison of Human Prothrombin, Factor IX (Christmas Factor), Factor X (Stuart Factor), and Protein S," <i>Biochem.</i> , 16:698-704 (1977).
	C45	Duchemin <i>et al.</i> "A New Assay Based on Thrombin Generation Inhibition to Detect Both Protein C and Protein S Deficiencies in Plasma," <i>Thromb. and Haemost.</i> , 71(3):331-338 (1994).
	C46	Edson <i>et al.</i> "Laboratory Diagnosis of Inherited Protein S Deficiency," <i>Am. J. Clin. Pathol.</i> , 94(2):176-186 (1990).
	C47	Esmon "The Roles of Protein C and Thrombomodulin in the Regulation of Blood Coagulation," <i>J. Biol. Chem.</i> , 264(9):4743-4746 (1989).
	C48	Esmon "The Regulation of Natural Anticoagulant Pathways," <i>Science</i> , 235:1348-1352 (1987).
	C49	Esmon "Protein C: Biochemistry, Physiology, and Clinical Implications," <i>Blood</i> , 62:1155-1158 (1983).
	C50	Exner <i>et al.</i> "A Sensitive Test Demonstrating Lupus Anticoagulant and its Behavioural Patterns," <i>Br. Haematol.</i> , 40:143-151 (1978).
	C51	Faioni <i>et al.</i> "Low Levels of the Anticoagulant Activity of Protein C in Patients with Chronic Renal Insufficiency: an Inhibitor of Protein C is Present in Uremic Plasma," <i>Thrombosis and Haemostasis</i> , 66(4):420-425 (1991).
	C52	Faioni <i>et al.</i> "Another Protein S Functional Assay is Sensitive to Resistance to Activated Protein C," <i>Thromb. and Haemost.</i> , 72(4):648 (1994).
	C53	Faioni <i>et al.</i> "Resistance to Activated Protein C in Nine Thrombophilic Families: Interference in a Protein S Functional Assay," <i>Thromb. and Haemost.</i> , 70(6):1067-1071 (1993).
	C54	Fernández <i>et al.</i> "Identification of Residues 413-433 of Plasma Protein S as Essential for Binding to C4b-binding Protein," <i>J. Biol. Chem.</i> , 268(22):16788-16794 (1993).
	C55	Fernández <i>et al.</i> "A Protein S Binding Site on C4b-binding Protein Involves β Chain Residues 31-45," <i>J. Biol. Chem.</i> , 269(4):2535-2540 (1994).
	C56	Folsom <i>et al.</i> "Prospective Study of Hemostatic Factors and Incidence of Coronary Heart Disease," <i>Circulation</i> , 96(4):1102-1108 (1997).
↓	C57	Forastiero <i>et al.</i> "Evaluation of Recently Described Tests for Detection of the Lupus Anticoagulant," <i>Thromb. Haemost.</i> , 72(5):728-733 (1994).

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## OTHER ART, JOURNAL ARTICLES, ETC.

<i>Ded</i>	C58	Gari <i>et al.</i> "The Influence of Low Protein S Plasma Levels in Young Women, on the Definition of Normal Range," <i>Thromb. Res.</i> , 73(2):149-152 (1994).
	C59	Giddings <i>et al.</i> "Chapter 12: Laboratory Support in the Diagnosis of Coagulation Disorders," <i>Clinics in Haematology</i> , 14(2):571-595 (1985).
	C60	Griffin <i>et al.</i> "Anticoagulant Protein C Pathway Defective in Majority of Thrombophilic Patients," <i>Blood</i> , 82(7):1989-1993 (1993).
	C61	Griffin <i>et al.</i> "Activated Protein C Resistance: Molecular Mechanisms," <i>Thromb. Haemost.</i> , 74(1) 444-448 (1995).
	C62	Halbmayer <i>et al.</i> "The Prevalence of Poor Anticoagulant Response to Activated Protein C (APC Resistance) Among Patients Suffering from Stroke or Venous Thrombosis and Among Healthy Subjects," <i>Blood Coag. and Fibrin.</i> , 5:51-57 (1994).
	C63	Han <i>et al.</i> "A Simple Functional Protein S Assay Using PROTAC®," <i>Clin. Lab. Haemat.</i> , 12:201-208 (1990).
	C64	Hardig <i>et al.</i> "The Amino-Terminal Module of the C4b-Binding Protein Beta-Chain Contains the Protein S-Binding Site," <i>J. Biol. Chem.</i> , 271(34):20861-20867 (1996).
	C65	Hemker <i>et al.</i> "Proteins Induced by Vitamin K Absence (PIVKAs) Effect of Coumarins on Circulating Clotting Factors," <i>Oral Anticoagulants</i> , Poller and Hirsch, eds., Arnold Press, London, 65-75 (1996).
	C66	Henkens <i>et al.</i> "Plasma Levels of Protein S, Protein C, and Factor X: Effects of Sex, Hormonal State and Age," <i>Thromb. Haemost.</i> , 74(5):1271-1275 (1995).
	C67	Hochuli <i>et al.</i> "Genetic Approach to Facilitate Purification of Recombinant Proteins with a Novel Metal Chelate Adsorbent," <i>Bio/Technology</i> , 1321-1325 (1988).
	C68	Hoffmann <i>et al.</i> "Comparison of Reagents for Determining the Activated Partial Thromboplastin Time," <i>Thromb. Haemost.</i> , 39:640-645 (1978).
	C69	Holmberg <i>et al.</i> "Assessment of Blood Coagulation and General Haemostasis," <i>Haemostasis and Thrombosis</i> (Bloom <i>et al.</i> Ed.), Churchill Livingston, London, 768-774 (1981).
	C70	Hoogendoorn <i>et al.</i> " $\alpha_2$ -Macroglobulin Binds and Inhibits Activated Protein C," <i>Blood</i> , 78(9):2283-2290 (1991).
	C71	Kalafatis <i>et al.</i> "Role of the Membrane in the Inactivation of Factor Va by Activated Protein C," <i>J. Biol. Chem.</i> , 268(36):27246-27257 (1993).
<i>↓</i>	C72	Kalafatis <i>et al.</i> "Proteolytic Events That Regulate Factor V Activity in Whole Plasma from Normal and Activated Protein C (APC)-Resistant Individuals During Clotting: An Insight into the APC-Resistance Assay," <i>Blood</i> , 87(11): 4695-4707 (1996).

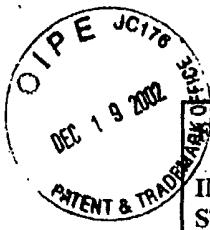
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## OTHER ART, JOURNAL ARTICLES, ETC.

QW	C73	Kamiya <i>et al.</i> "Inherited Deficiency of Protein S in a Japanese Family with Recurrent Venous Thrombosis: A Study of Three Generations," <u>Blood</u> , 67 (2): 406-410 (1986).
	C74	Kane <i>et al.</i> "Blood Coagulation Factors V and VIII: Structural and Functional Similarities and Their Relationship to Hemorrhagic and Thrombotic Disorders," <u>Blood</u> , 71(3):539-555 (1988).
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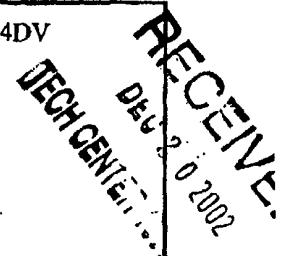
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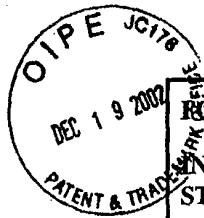
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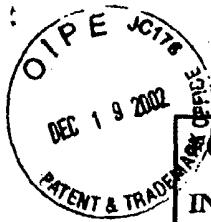
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